



6-15-07

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Express Mail Label No. EV 882 291 817 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: OTTOBONI, Thomas B. et al.

Serial No.: 10/690,045

Filed: October 20, 2003

For: MICROPARTICLES USEFUL AS
ULTRASONIC CONTRAST AGENTS AND
FOR DELIVERY OF DRUGS INTO THE
BLOODSTREAM

Docket No: 375430-002T1D1C1 (355479)

Confirmation No.: 3501

Group Art Unit: 1615

Examiner: CAPPS, Kevin J.

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §§ 1.97 and 1.98, Applicant submits herewith patents, publications and/or other information (listed below and/or on the attached Substitute Form PTO 1449) that may be material to the examination of the captioned application, and in respect of which there may be a duty of disclosure as set forth in 37 CFR § 1.56, for consideration and to be made of record in the captioned application by the U.S. Patent and Trademark Office.

COMMENTS ON CERTAIN REFERENCES

This application is a continuation of application No. 09/758,988, filed January 11, 2001, currently pending (US 2001/0012522; Cite No. A38), which is a divisional of application No. 09/070,474, filed April 30, 1998 (now U.S. Patent No. 6,193,951; cited by the Examiner in an Office Action dated December 4, 2006), which is a continuation-in-part of application No. 08/847,153, filed April 30, 1997, now abandoned. Cite Nos. C3-C5 are reports received from the International Bureau in the international counterpart of the grandparent '951 patent (WO 98/48783; Cite No. B17). Cite Nos. C12-C24 are Search Reports and Office Actions received in foreign counterparts of the grandparent '951 patent. Cite Nos. C25-C26 are Office Actions mailed by the U.S. Patent and Trademark Office in the non-abandoned great grandparent '153 application. Cite Nos. C27-C28 are Office Actions mailed by the U.S. Patent and Trademark Office in the grandparent '951 patent. Cite Nos. C29-C33 are Office Actions mailed by the

U.S. Patent and Trademark Office in the parent '988 application. Co-pending application Nos. 09/637,576 (Cite No. A41; cited by the Examiner in an Office Action dated December 4, 2006), application publication No. 2005/0113697 (Cite No. A40; a divisional of Cite No. A41) and application No. 10/977,100 (Cite No. A42; cited by the Examiner in an Office Action dated December 4, 2006) are not related to the instant application, but disclose inventions that are of a similar ilk. Cite No. B19 is the international counterpart of Cite Nos. A40 and A41. Cite Nos. C7-C8 are search reports issued in Cite No. B19, Cite No. C9 is a search report issued in the European counterpart of Cite Nos. A40 and A41, and Cite Nos. C34-C40 are Office Actions mailed in the '516 application (Cite No. A41).

The international counterpart of Cite No. A42 published after the filing date of the instant application. Accordingly, it is not being cited on the attached Substitute Form PTO 1449. No Office Actions have been mailed in Cite No. A42.

1. ☒ In accordance with 37 CFR 1.98, accompanying this Information Disclosure Statement are:

1a. ☒ copies of: (i) each foreign patent listed on the attached Substitute Form PTO 1449; (ii) each publication listed on the attached Substitute Form PTO 1449, or that portion which caused it to be listed, *other than* U.S. patents and U.S. patent application publications; (iii) for each pending unpublished U.S. application, a copy of the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, except for Cite Nos. A41 and A42, which the Office has already considered, as evidenced by rejections stated in the Office Action dated December 4, 2006; and (iv) other information, or that portion which caused it to be listed herein or on the attached Substitute Form PTO-1449 (37 CFR § 1.98(a)(2)); and/or

1b. ☒ a concise explanation of relevancy, or an English language translation, of non-English language publications listed on the attached Substitute Form PTO-1449 (37 CFR § 1.98(a)(3)(i) & (ii)) as described in the table below:

Cite No.	English Language Equivalent Cite No.
B7 – DE 44 16 818	A32 – US 6,120,805 by Spenlehauer et al., Schering AG
B15 – WO 89/06978	B5 – AU 30351/89 by Stein et al., Schering AG

2. ☒ Copies of Cite Nos. B8-B14 and B17 listed on the attached Substitute Form PTO 1449 are not enclosed herewith, because the information was previously submitted to, or cited by, the U.S. Patent and Trademark Office in parent and grandparent application Serial Nos. 09/758,988 and 08/847,153, of which the captioned application claims benefit under 35 U.S.C. § 120, and the Information Disclosure Statements submitted in those applications complied with paragraphs (a) through (c) of 37 CFR § 1.98 (37 CFR § 1.98(d)).

3. ☐ This Information Disclosure Statement is filed under 37 CFR § 1.97(b):

3a. ☐ within three months of the filing date of a national application other than a continued prosecution application under 37 CFR § 1.53(d);

3b. ☐ within three months of the entry of the national stage as set forth in 37 CFR § 1.491 in an international application;

3c. ☐ before the mailing of a first Office Action on the merits; *or*

3d. ☐ before the mailing of a first Office Action, and after the filing of a Request for Continued Examination under 37 CFR § 1.114. **Accordingly, no certification or fee is required.**

4. ☒ This Information Disclosure Statement is filed under CFR § 1.97(c) after the period specified by CFR § 1.97(b), but before the mailing date of any of a final Office Action under 37 CFR § 1.113, a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by one of:

4a. ☐ the statement specified in 37 CFR § 1.97(e); *or*

4b. ☒ the fee set forth in 37 CFR § 1.17(p).

5. ☐ This Information Disclosure Statement is filed under 37 CFR § 1.97(d) after the period specified by CFR § 1.97(c), but on or before payment of the issue fee, and is accompanied by both of:

5a. ☐ the statement specified in 37 CFR § 1.97(e); *and*

5b. ☐ the fee set forth in 37 CFR § 1.17(p).

6. ☐ Certification Statement (*applicable if Item 4a or 5a is checked*)

6a. ☐ In accordance with 37 CFR § 1.97(e)(1), the undersigned hereby states that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; *or*

6b. ☐ In accordance with 37 CFR § 1.97(e)(2), the undersigned hereby states that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making a reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

7. ☒ Fee Statement and/or Authorization (*applicable if Item 4b or 5b is checked*)

7a. ☒ The fee set forth in 37 CFR § 1.17(p) is:

☒ enclosed; *or*

☐ to be charged to Dechert LLP Deposit Account No. 50-2778 (**Order No.:** _____).

8. ☐ Additional materials (*if applicable*)

8a. ☐ a continuation application under 37 CFR § 1.53(b)(1) is filed concurrently herewith;

8b. ☐ a Request for Continued Examination under 37 CFR § 1.114 is filed concurrently herewith; *or*

8c. ☐ a Petition to Withdraw from issue under 37 CFR § 1.313(c)(2).

As specified in 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material information as defined in 37 CFR § 1.56(a) exists.

As specified in 37 CFR § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any information cited herein is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

Moreover, while the patents, publications and/or other information disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR § 1.56, the Disclosure is not intended to constitute an admission that any patents, publications and/or other information included or referred to herein is "prior art" to the captioned application unless specifically designated as such.

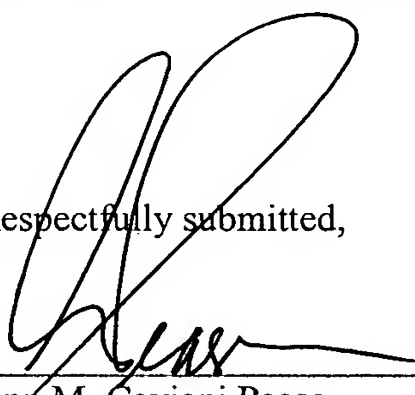
It is respectfully submitted that this Information Disclosure Statement is in compliance with 37 CFR § 1.98 and MPEP § 609. Accordingly, consideration of the foregoing and prompt return of a copy of the enclosed Substitute form PTO 1449 with the Examiner's initials in the left column in accordance with MPEP § 609 are respectfully requested.

No fees beyond those mentioned in Item 7 are believed due in connection with the Information Disclosure Statement. However, the Commissioner is authorized to charge any additional required fees, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 (**Order No. 375430-002T1D1C1 (355479)**).

Date: June 13, 2007

DECHERT LLP
Customer No. 37509
Tel: 650.813.4800
Fax: 650.813.4848

Respectfully submitted,



Ann M. Caviani Pease
Reg. No. 42,067



Express Mail No. EV 882 291 817 US

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/690,045
				Filing Date	October 20, 2003
				First Named Inventor	Ottoboni <i>et al.</i>
				Group Art Unit	1615
				Examiner Name	Kevin J. Capps
				Confirmation No.	3501
Sheet	1	of	6	Attorney Docket No.	375430-002T1D1C1 (355479)

U.S. PUBLISHED DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Publication Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A03	US-3,743,604	A	Schoring et al.	07-03-1973
	A04	US-4,718,433	A	Feinstein	01-12-1988
	A05	US-4,880,634	A	Speiser	11-14-1989
	A06	US-5,041,292	A	Feijen	08-20-1991
	A07	US-5,271,961	A	Mathiowitz et al.	12-21-1993
	A08	US-5,310,540	A	Giddey et al.	05-10-1994
	A09	US-5,425,366	A	Schering	06-20-1995
	A10	US-5,501,863	A	Rossling et al.	03-26-1996
	A11	US-5,518,709	A	Sutton et al.	05-21-1996
	A12	US-5,542,935	A	Unger et al.	08-06-1996
	A13	US-5,560,364	A	Porter	10-01-1996
	A14	US-5,562,893	A	Lohrmann	10-08-1996
	A15	US-5,565,215	A	Gref et al.	10-15-1996
	A16	US-5,569,468	A	Modi	10-29-1996
	A17	US-5,611,344	A	Bernstein et al.	03-18-1997
	A18	US-5,620,883	A	Shao et al.	04-15-1997
	A19	US-5,679,377	A	Bernstein et al.	10-21-1997
	A20	US-5,707,607	A	Quay	01-13-1998
	A21	US-5,711,933	A	Bichon et al.	01-27-1998
	A22	US-5,730,955	A	Lormann	03-24-1998
	A23	US-5,837,221	A	Bernstein et al.	11-17-1998
	A24	US-5,863,520	A	Bichon et al.	01-26-1999
	A25	US-5,919,434	A	Dugstad et al.	07-06-1999
	A26	US-5,922,304	A	Unger	07-13-1999
	A27	US-5,948,387	A	Unger et al.	09-07-1999
	A28	US-6,028,066	A	Unger	02-22-2000
	A29	US-6,045,777	A	Church et al.	04-04-2000
	A30	US-6,068,857	A	Weitschies et al.	05-30-2000
	A31	US-6,120,805	A	Spenehauer et al.	09-19-2000
	A32	US-6,139,819	A	Unger et al.	10-31-2000
	A33	US-6,200,548	B1	Bichon et al.	03-13-2001
	A34	US-6,205,352	B1	Carroll	03-20-2001
	A35	US-6,207,135	B1	Rossling et al.	03-27-2001
	A36	US-6,224,554	B1	Tickner et al.	05-01-2001

Examiner Signature		Date Considered	13667889.1.BUSINESS
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation or translation of abstract is attached.

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U.S. PUBLISHED DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Publication Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A37	US-6,444,192	B1	Mattrey	09-03-2002
	A38	US-2001/0012522	A1	Ottoboni et al.	08-09-2001
	A39	US-2003/0118649	A1	Gao et al.	06-26-2003
	A40	US-2005/0113697	A1	Ottoboni et al.	05-26-2005
	A41	USSN 09/637,516		Ottoboni et al.	08-11-2000 filing date
	A42	USSN 10/977,100		Ottoboni et al.	10-28-2004 filing date
	A43	US-5,770,222	A	Unger et al.	06-23-1998
	A44				

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ²	
		Office	Number	Kind Code (if known)			Yes	No
	B05	AU	30351/89	B	03-18-1998	Schering AG		
	B06	CA	2 342 912	A1	03-09-2000	Point Biomedical Corp.		
	B07	DE	44 16 818	A1	11-16-1995	Schering AG	X	
	B08	EP	0 224 934	B1	06-10-1987	Feinstein, Steven B.		
	B09	EP	0 398 935	B1	11-28-1990	Schering AG		
	B10	EP	0 441 468	B1	08-14-1991	Schering AG		
	B11	EP	0 512 693	A1	11-11-1992	Delta Biotechnology Ltd.		
	B12	EP	0 523 183	B1	01-20-1993	Rhone Poulenc Rorer SA		
	B13	EP	0 681 843	A2	11-15-1995	Andaris Ltd.		
	B14	GB	2 256 183	B	12-02-1992	Delta Biotechnology Ltd.		
	B15	WO	89/06978	A	08-10-1989	Schering AG	X	
	B16	WO	92/18164	A1	10-29-1992	Delta Biotechnology Ltd.		
	B17	WO	98/48783	A	11-05-1998	Point Biomedical Corp.		
	B18	WO	98/48838	A1	11-05-1998	Nycomed Imaging AS		
	B19	WO	01/12071	A	02-22-2001	Point Biomedical Corp.		

Examiner Signature		Date Considered	13667889.1.BUSINESS
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				Application Number	10/690,045
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				First Named Inventor	Ottoboni <i>et al.</i>
				Group Art Unit	1615
				Examiner Name	Kevin J. Capps
				Confirmation No.	3501
Sheet	3	of	6	Attorney Docket No.	375430-002T1D1C1 (355479)

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ²	
			Yes	No
	C03	International Search Report from PCT/US98/08827 dated 07-30-1998 (Docket No. 375430-002WO)		
	C04	Written Opinion from PCT/US98/08827 dated 03-11-1999 (Docket No. 375430-002WO)		
	C05	International Preliminary Examination Report from PCT/US98/08827 dated 03-16- 2000 (Docket No. 375430-002WO)		
	C06	International Search Report from PCT/US00/22097 dated 10-13-2000 (Docket No. 375430-009WO)		
	C07	Written Opinion from PCT/US00/22097 dated 06-15-2001 (Docket No. 375430-009WO)		
	C08	International Preliminary Examination Report from PCT/US00/22097 dated 09-27- 2001 (Docket No. 375430-009WO)		
	C09	European Search Report (supplementary partial) from EP Serial No. 00954000.6 dated 09-15-2004 (Docket No. 375430-009EP)		
	C10	International Search Report from PCT/US04/36537 dated 05-30-2006 (Docket No. 375430-016WO)		
	C11	Written Opinion from PCT/US04/36537 dated 05-30-2006 (Docket No. 375430-016WO)		
	C12	Office Action from AU Serial No. 71730/98 dated 11-13-2000 (Docket No. 375430-002AU)		
	C13	Office Action from CA Serial No. 2,289,088 dated 02-22-2006 (Docket No. 375430-002CA)		
	C14	Office Action from DE Serial No. 198 82 362.2-41 dated 06-26-2006 (Docket No. 375430-002DE)	X	
	C15	Office Action from DE Serial No. 198 82 362.2-41 dated 02-05-2007 (Docket No. 375430-002DE)	X	
	C16	Search Report from EP Serial No. 98918899.0 dated 01-26-2004 (Docket No. 375430-002EP)		
	C17	Office Action from EP Serial No. 98918899.0 dated 06-10-2005 (Docket No. 375430-002EP)		

Examiner Signature		Date Considered	13667889.1.BUSINESS
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Sheet	4	of	6	Attorney Docket No.	375430-002T1D1C1 (355479)

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ²	
			Yes	No
	C18	Office Action from EP Serial No. 98918899.0 dated 03-17-2006 (Docket No. 375430-002EP)		
	C19	Office Action from GB Serial No. 9925661.2 dated 11-27-2000 (Docket No. 375430-002GB)		
	C20	Office Action from GB Serial No. 9925661.2 dated 07-06-2001 (Docket No. 375430-002GB)		
	C21	Office Action from GB Serial No. 9925661.2 dated 09-25-2001 (Docket No. 375430-002GB)		
	C22	Office Action from MX Serial No. 999986 dated 05-2003 (Docket No. 375430-002MX)	X	
	C23	Office Action from MX Serial No. 999986 dated 11-2003 (Docket No. 375430-002MX)	X	
	C24	Office Action from MX Serial No. 999986 dated 09-2005 (Docket No. 375430-002MX)	X	
	C25	Office Action from US Serial No. 08/847,153 dated 06-15-1998 (Docket No. 375430-002US)		
	C26	Office Action from US Serial No. 08/847,153 dated 02-22-1999 (Docket No. 375430-002US)		
	C27	Office Action from US Serial No. 09/070,474 dated 12-22-1999 (Docket No. 375430-002T1US)		
	C28	Office Action/Notice of Allowance from US Serial No. 09/070,474 dated 12-22-1999 (Docket No. 375430-002T1US)		
	C29	Office Action from US Serial No. 09/758,988 dated 06-27-2002 (Docket No. 375430-002T1D1US)		
	C30	Office Action from US Serial No. 09/758,988 dated 02-26-2003 (Docket No. 375430-002T1D1US)		
	C31	Office Action from US Serial No. 09/758,988 dated 06-03-2004 (Docket No. 375430-002T1D1US)		
	C32	Office Action from US Serial No. 09/758,988 dated 01-27-2005 (Docket No. 375430-002T1D1US)		

Examiner Signature		Date Considered	13667889.1.BUSINESS
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Sheet	5	of	6	Attorney Docket No.	375430-002T1D1C1 (355479)

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS				
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			Yes	No
	C33	Office Action from US Serial No. 09/758,988 dated 01-19-2007 (Docket No. 375430-002T1D1US)		
	C34	Office Action from US Serial No. 09/637,516 dated 12-10-2001 (Docket No. 375430-009US)		
	C35	Office Action from US Serial No. 09/637,516 dated 06-27-2002 (Docket No. 375430-009US)		
	C36	Office Action from US Serial No. 09/637,516 dated 12-31-2002 (Docket No. 375430-009US)		
	C37	Office Action from US Serial No. 09/637,516 dated 09-23-2003 (Docket No. 375430-009US)		
	C38	Office Action from US Serial No. 09/637,516 dated 07-01-2004 (Docket No. 375430-009US)		
	C39	Office Action from US Serial No. 09/637,516 dated 10-19-2005 (Docket No. 375430-009US)		
	C40	Office Action from US Serial No. 09/637,516 dated 01-23-2007 (Docket No. 375430-009US)		
	C41	Andre et al., 1990, "Physical and Acoustical Properties of Perfluorooctylbromide, an Ultrasound Contrast Agent," Investigative Radiology 25(9):983-987		
	C42	Andre et al., 1993, "Enhancement of the Echogenicity of Flowing Blood by the Contrast Agent Perflubron," Investigative Radiology 28(6):502-506		
	C43	Bazile et al., 1992, "Body Distribution of Fully Biodegradable [14C]-poly(lactic acid) Nanoparticles Coated With Albumin after Parenteral Administration to Rats," Biomaterials 13(15):1093-1102		
	C44	DeCicco et al., 1988, "Lymphoscintigraphy and Radioguided Biopsy of the Sentinel Axillary Node in Breast Cancer," J. Nucl. Med. 39(12):2080-2084		
	C45	DeCicco et al., 1998, "Intraoperative Localization of the Sentinel Node in Breast Cancer: Technical Aspects of Lymphoscintigraphic Methods," Semi. Surg. Oncol. 15:268-271		
	C46	Forsberg et al, 2001, "Physics of Constrast Microbubbles," Chapter 2 of Ultrasound Contrast Agents Text Book, 2 nd Edition, Martin Dunitz Ltd., pp. 15-24		

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Sheet	6	of	6	Attorney Docket No.	375430-002T1D1C1 (355479)

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			Yes	No
	C47	Hughes et al., 2001, "Comparison of Ultrasound Scattering Properties of Optison® with a Liquid Perfluorocarbon Nanoparticle Contrast Agent," 2001 IEEE Ultrasonics Symposium, pp. 1675-1678		
	C48	Kremkau, Frederick W., 1988, "Diagnostic Ultrasound: Principles and Instruments," 5 th Edition, W.B. Saunders Company pp. 1-3, 10-11, 24-25, 32-33, 38-39, 48-49, 60-61, 82-83, 86-87, 106-107, 114-115, 144-145, 180-181, 188-189, 218-223, 234-235, 270-271, 282-283, 336-337, 362-365, 420-421, 452-453 and 472-473		
	C49	Linehan et al., 1999, "Sentinel Lymph Node Biopsy in Breast Cancer: Unfiltered Radioisotope is Superior to Filtered," J. Am. Coll. Surgery 188(4):377-381		
	C50	Lubbers et al., 1976, "An Ultrasonic Detector for Microgasemboli in a Bloodflow Line," An Ultrasound in Med. & Biol. 2:301-310		
	C51	Mattrey et al., 1982, "Perfluorooctylbromide: A Liver/Spleen-Specific and Tumor-Imaging Ultrasound Contrast Material," Radiology 145:759-762		
	C52	Medwin, 1977, "Counting Bubbles Acoustically: A Review," Ultrasonics 15:7-13		
	C53	Ngo et al., 2000, "Evaluation of Liquid Perfluorocarbon Nanoparticles as a Blood Pool Contrast Agent Utilizing Power Doppler Harmonic Imaging," 2000 IEEE Ultrasonic Symposium, pp. 1931-1934 (w/ Fig. 3 & 4 enlarged for enhancement) (total of 6 sheets)		
	C54	Ottoboni et al., "Microparticles Useful as Ultrasonic Contrast Agents and for Drug Delivery," 1999, Database Derwent on East AN 1999-009363. WO98/48783 11/1998 Abstract		
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	C56	Swartz, 2001, "The Physiology of the Lymphatic System," Advance Drug Delivery Reviews 50:3-20		

Examiner Signature		Date Considered	13667889.1.BUSINESS
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